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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PONNALURI, PADMASHRI	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/986,527	BARANY ET AL.	
	Examiner	Art Unit	
	Padmashri Ponnaluri	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *1-14 and 25-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/26/04 and 6/21/0*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendments and response filed on 6/21/04 have been fully considered and entered into the application.

2. Claims 1-37 are currently pending in this application.

3. Claims 1-14, 25-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11122003.

4. Applicants arguments regarding the restriction of claims 1-14, 25-37 have been considered and are not persuasive, because the

5. This application contains claims 1-14, 25-37 drawn to an invention nonelected with traverse in Paper No. 11122003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

6. Claims 15-24 are currently being examined in this application.

Information Disclosure Statement

7. The references in the information disclosure statements filed on 4/26/04 and 6/21/04 have been fully considered.

Specification

8. The objection to the specification set forth in the previous office action (4/23/04) has been withdrawn in view of the submission of the copies of the pages.

Withdrawn Rejections

9. The rejections of lack of antecedent basis in claims 15 and 16 have been withdrawn in view of the amendments to the claims.

Maintained Rejections

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. Claims 15-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons of record set forth in the office action mailed on 4/23/04.

11. Claims 15, 19-23 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,412,087 (McGall et al) (US Patent application 07/874,849 filed on 4/24/92) for the reasons of record set forth in the previous office action mailed on 4/23/04.

12. Claims 15, 22, 24 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,723,320 (Dehlinger) (US Patent application 08/520,730 filed on 8/29/95).

13. Claims 15-24 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,156,501 (McGall et al) (US Patent application 08/520,730 filed on 8/29/95).

14. Claims 15, 17-18, 20-22, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 5,700637 (Southern) and US patent 5,594,121 (Froehler et al).

New Claim Rejections Necessitated by the Amendment

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

16. Claims 15-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

17. Claim 16 recites the limitation "said oligonucleotide analogue probe" in line 3. There is insufficient antecedent basis for this limitation in the claim.

18. Claim 16 recites the limitation "said complementary target nucleic acid" in line 3 and line 5. There is insufficient antecedent basis for this limitation in the claim.

19. Claim 16 recites the limitation "the perfect complement " in line 5. There is insufficient antecedent basis for this limitation in the claim.

Response to Arguments

20. Applicant's arguments filed on 6/21/04, regarding the indefiniteness rejection of claims 15-24 have been fully considered but they are not persuasive.

a) Applicants argue that 'the limitations which form the basis for this ground of rejection are all found in the claims of McGall `501. ..... Having made decisions in McGall `501, it is improper to come to a different decision here. For this reason alone the indefiniteness rejection should be withdrawn.'

Applicant's arguments have been considered and are not persuasive, because the Office recognizes that each case must be decided on its merits, not based on another application disclosure and/or prosecution history.

b) Applicants' arguments regarding indefiniteness rejection of the phrase 'oligonucleotide analogue array' should be withdrawn have been considered and are not persuasive.

Claim 15 recites 'oligonucleotide analogue array', it is not clear what does applicants mean by analogue array. Does applicants mean that the array has sequences, which are analogous to the target sequences, or does applicants mean that the analogue array has oligonucleotide analogies used in the probe synthesis. The metes and bounds of the 'analogue array' are not clear. Applicants are requested to amend the claim to clarify the issue. The specification teaches the use of peptide nucleotide analogues in the array synthesis, if applicants mean that the instant claim array is prepared using PNAs. Applicants are requested to amend the claim.

The phrase 'analogue array' has various different interpretations as stated in the previous office action. 'an analogue is considered as structural derivative of parent compound', thus the instant 'analogue array' is a structural derivative of the parent array, i.e., the array having derivative or different nucleic acid sequences would read on the instant phrase, or the array is structurally analogous (i.e, the arrangement of the probes) to the parent array. Thus, it is not clear what would infringe the instant claim. Applicants argue that the specification in page 7 and page 11 discuss the 'concept of an array of oligonucleotides.' And the 'concept of nucleotide analogues to form the capture oligonucleotides on the array is also fully described in the present application in pages 8 and page 40. The specification in page 8, discloses 'peptide nucleotide analogue (PNA)'; and page 40 discloses 'synthetic oligonucleotides are prepared as either DNA or PNA..' which are not a definition for 'analogue array.' In view of applicants response it is considered that the invention is drawn to PNA array.

c) Applicants response to the rejection of the phrase 'similar hybridization stability across the array' has been considered, and is not persuasive.

Applicants argue that one of ordinary skill in the art would fully understand what is meant by the 'similar hybridization stability across the array' limitation. Applicants argue that 'oligonucleotide capture can be optimized by narrowing the thermal stability (Tm) difference

between duplexes formed by capture oligonucleotides and the complementary addressable specific portions hybridized to one another, this Tm difference results from differences in GC/AT content. The specification in page 49 discloses that 'when attempting to detect multiple mutations simultaneously, it becomes difficult or impossible to optimize hybridization conditions. In contrast, the present invention is a general method for high specificity detection of correct signal, independent of target sequences, under uniform hybridization conditions.' However, the specification does not teach or define what is the meaning of 'similar hybridization stability across the array.' In the phrase 'similar hybridization stability across the array', the term 'similar' is a relative term, similar to what degree; and 'hybridization stability' does applicants mean the stability after the hybridization with the target or before, and further the hybridization stability is based on several factors, such as temperature, pH or the nucleotides present in the probe; and 'across the array', does applicants mean all the probes in the array or probes in a horizontal row or between certain defined areas in the array. Thus, in the absence of a definition for 'similar hybridization stability across the array', and in view of different various interpretations (no standard interpretation), the phrase is considered as indefinite.

d) Applicants arguments and response to the rejection of claim 16 have been fully considered and entered into the application.

The instant claim 16 recites that the one of the oligonucleotide analogue probe has increased thermal stability, as compared to an oligonucleotide probe without nucleotide analogue that is perfect complement to complementary target nucleic acid.

In claim 16, applicants have not addressed how the array has 'similar hybridization stability across the array', if one of the probe has increased thermal stability. The claim 15

limitations, 'similar hybridization stability across the array' contradicts in view of the instant amended claim 16.

Applicants assert that the instant claim 16 does not miss any essential subject matter. Applicants assertions have been fully considered and are not persuasive, since any one probe in the array to have increased thermal stability as compared to an oligonucleotide probe without the nucleotide analogues, the presence or knowledge of the analogue used in the probe is essential, such that one skilled in the art would be able to determine whether the probe has increased stability. And further the hybridization stability is dependent on the nucleotide composition (GC/AT content), and the use of one single oligonucleotide analogue increases the stability, which is essential in the claimed method array such that the stability is increased as compared to the nucleotide probe without the nucleotide analogue in the probe.

And further applicants state that PTO issued McGall '501, it implicitly recognized that claims of the same breadth as claim 16 satisfy the provisions of 35 USC 112, 2nd paragraph. Applicant's statements have been considered and are persuasive, because each application is examined on its merits, and the prosecution history and/or disclosure of McGall '501 patent would not effect the prosecution of the instant application.

For the reasons of above, the rejections under 35 USC. 112, second paragraph have been maintained.

21. Applicant's arguments filed on 6/21/04, regarding the rejection of claims 15, 19-23 over McGall, US Patent 5,412,087 (McGall '087), have been fully considered but they are not persuasive.

The instant claim briefly recites a method of analyzing interactions between an

oligonucleotide target and an oligonucleotide analogue probe comprising: a)synthesizing an oligonucleotide analogue array; b) exposing said oligonucleotide analogue probe array to oligonucleotide target; c) determining whether an oligonucleotide analogue probe of the array binds to at least one target nucleic acid.

McGall et al teach spatially addressable arrays of oligonucleotides on a solid substrate (refers to the instant claim array). The reference teaches that the arrays can be used in assays to detect the presence of complementary nucleic acid in sample (e.g., see the abstract). The reference teaches that spatially addressed irradiation of predefined regions on the surface permits immobilization of oligonucleotides and other polymers at the activated regions of the surface. The reference teaches that nucleic acids such as RNA and DNA are the polymers and also synthetic, non-naturally occurring monomers can be used to construct a biological polymer (e.g., see column 4) (refers to the oligonucleotide analogies of the instant claims). The reference teaches that the monomers are immobilized to the solid substrate in the predefined regions by selectively irradiating predefined regions to activate photoactivatable thiol groups (e.g., see column 5)(refers to instant claims 19 and 23). The reference teaches that the substrate can be glass slides (e.g., see column 6) (refers to instant claims 21-22). The reference teaches that array of anti-ligands permits simultaneous screening of liquid sample for ligands having high affinities for certain anti-ligands of the matrix. The reference teaches that the oligonucleotide solution was applied to the slide (refers to instant claim 20). The reference teaches that the arrays were tested for ability to hybridize specifically with a complementary oligonucleotide or target nucleic acid. Thus, the reference clearly anticipates the claimed invention.

Applicants argue that McGall '087 does not teach an oligonucleotide analogue array. Applicants arguments are not persuasive, because McGall et al teach spatially addressable arrays of oligonucleotides on a solid substrate, and further teach the use of nucleic acids such as RNA and DNA and also synthetic, **non-naturally occurring monomers** (which refers to instant claim nucleotide analogues) to construct a biological polymer. Thus McGall et al teach oligonucleotide analogue array. The reference teaches assay for screening the probes on the array by hybridizing with target nucleic acids. McGall et al do not specifically teach that the oligonucleotide arrays have 'similar hybridization stability across the array', however in view of the absence of clear

definition of the phrase, the reference array is considered to have 'similar hybridization stability across the array.' The reference teaches the same probe sequences (CAP2) (or anti-ligands) immobilized to the surface (example 3), and expose to the same reagents, which in result would have the similar or same hybridization stability. Further, the specification in example 7 teaches the oligonucleotide array of two different probes (CAP2 and CAP5), and which is exposed to hybridization to different ligands, which refers to the instant claim similar hybridization stability. Note the 'similar' means not completely identical. Thus, the rejections of record have been maintained for the reasons of record.

22. Applicant's arguments filed on 6/21/04 regarding the rejection of claims 15, 22, 24 over Dehlinger (US Patent 5,723,320) have been fully considered but they are not persuasive.

Dehlinger et al teach positionally addressable polynucleotide arrays. The reference teaches that the method employs an array of different sequence oligonucleotides having a unique, known combinatorial sequence associated with each addressable region in the array ((e.g., see column 2) (refers to instant claim array). The reference teaches that the array is contacted with gene-probe templates (e.g., see column 2)(refers to the instant claim plurality of oligonucleotide targets). The reference teaches that the contacting is done under complementary strand hybridization conditions (e.g., see column 2). The reference teaches that the oligonucleotides may include nucleotide analog subunits (refers to instant claim oligonucleotide analog). The reference teaches that eh position0addresable array of different oligonucleotides are formed on a wound or extended filament (e.g., see column 3) (refers to instant claim solid substrate). The reference teaches that the suitable polymers for the coating are polystyrene (e.g., see column 7) (refers to instant claim 22). The reference teaches that the use of 3' phosphromidate activated nucleoside (e.g., see column 8) (refers to instant claim 24). The reference teaches that the probe array of the invention is used in sequencing and in diagnostics. The gene probe array of the invention is contacted with labeled DNA sample (refers to the target oligonucleotide sequence of the instant claims) (refers to step b) of the instant claims) (e.g., see column 13). The reference teaches that the sample binding to the array has been identified (refers to instant claim step c). The reference clearly anticipates the claimed invention.

Applicants argue that Dehlinger does not disclose an oligonucleotide analogue array comprising a plurality of oligonucleotide analogue probes where the plurality oligonucleotide analogue probes bind to complementary target nucleic acids with similar hybridization across the array.

Dehlinger teaches positionally addressable polynucleotide arrays, which refer to instant claim oligonucleotide probe array. The reference teaches the subunits of the array forming the oligonucleotide may include or be composed primarily of nucleotide analogue subunits, which refer to the oligonucleotide analogues of the instant claims. And further the reference teaches that the array is contacted with a set of gene-probe templates (refer to the target of the instant claims) under complementary strand hybridization conditions, such that each member in the target set becomes hybridized, which refers to the 'similar hybridization stability across the array' of the instant claims. The reference clearly teaches the claimed invention.

23. Applicant's arguments filed on 6/21/04, regarding the rejection of claims 15-24 over McGall (US Patent 6,156,501) (McGall `501) have been fully considered but they are not persuasive.

Claims 15-24 are copied from US Patent 6,156,501 (McGall et al) (US Patent application 08/630,427, filed on 4/3/96).

Claims 35, 37, 43-44, 46-48, and 50 of the '501 patent are exactly same as the instant claims 15-24. The '501 patent or the 08/630,427 application is a CIP of 08/440,742, filed on 5/10/95. The 08/440,742 application discloses the oligonucleotide analogues in the synthesis of array. Thus, the '501 patent claims have effective filing date of at least 5/10/1995. The effective filing date of current application 09/986,527 is 2/9/96. Thus the reference the '501 patent clearly is a prior art under 35 USC. 102 (e).

Applicant's arguments regarding the Request for Declaration of Interference, and showing by 37 CFR 1.608 (b) , and accompanying declarations to provoke interference with McGall '501 patent. Applicant's arguments have been considered and are not persuasive. Because the reference (McGall `501) has effective filing date of at least 5/10/95 (prior to the instant application filing date), and the interference has not been declared yet, the rejection under 35 USC. 102 (e) are proper and are maintained until the case is ready for interference.

24. Applicant's arguments filed on 6/21/04, regarding the rejection of claims 15-24, over the combined teachings of Southern and Froehler, have been fully considered but they are not persuasive.

The instant claim briefly recites a method of analyzing interactions between an oligonucleotide target and an oligonucleotide analogue probe comprising: a)synthesizing an oligonucleotide analogue array; b) exposing said oligonucleotide analogue probe array to oligonucleotide target; c) determining whether an oligonucleotide analogue probe of the array binds to at least one target nucleic acid.

Southern teaches methods for analyzing a polyucleotide sequence. The reference teaches an array of oligonucleotides on a glass plate (refers to the instant claim array and claims 21-22) (e.g., see abstract). The array of the reference on a glass plate is use din a hybridization reaction. The reference teaches that the polynucleotide sequences of the array of chosen length, the different oligonucleotides occupying separate cells of the array (e.g., see column 1)(refers to the known locations of the instant claim). The reference teaches the use of monomers comprising phosphromidite nucleotides (e.g., see column 9). The reference teaches that in the hybridization reaction the array is explored with labeled probe, and the probe may comprise labeled sequences amplified from the genomic DNA by polymerase chain reaction (e.g., see column 2) (refers to instant claims 17-18).

The claimed invention differs from the prior art teachings by reciting oligonucleotide analogue array. Southern teaches the method for synthesis of oligonucleotide array and use of the array in a method of detecting the target sequences. Southern does not teach the oligonucleotide analog array. Froehler et al teach modified purine-based oligomers (nucleotide analogues), which have enhanced ability to form duplexes as compared to the use of

conventional bases (e.g., see abstract). The reference teaches that the enhanced binding affinity of the reference oligomers is an advantage for their use as probes and primers (e.g., see column 32). The reference teaches that the oligomers having enhanced affinity for complementary nucleic acid sequences or enhanced nuclease stability would have improved properties for diagnostic applications (e.g., see column 3). The reference teaches that the oligomers of the invention can be formed using standard solid phase oligomer synthesis (e.g., see column 11). The reference teaches the use of protecting groups during synthesis, and the use of phosphoramidite as coupling groups (e.g., see column 12) (refers to instant claim 24).

It would have been obvious to one skilled in the art at the time the invention was made to use the oligonucleotide analogs taught by Froehler et al in the array of oligonucleotide taught by Southern because Froehler et al teaches that the oligomers having enhanced affinity for complementary nucleic acid sequences or enhanced nuclease stability would have improved properties for diagnostic applications. A person skilled in the art would have been motivated to use the modified oligomers taught by Froehler et al with the oligonucleotide array of Southern and use the array in the diagnostic assays because Froehler et al teaches the advantages of the oligomers in the diagnostic assays.

In response to applicant's arguments against the references (Southern and Froehler) individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Southern teaches the method for synthesis of oligonucleotide array and use of the array in a method of detecting the target sequences. Froehler et al teach modified purine-based oligomers (nucleotide analogues), which have enhanced ability to form duplexes as compared to the use of conventional bases (e.g., see abstract). Froehler et al teach that the enhanced binding affinity of the purine based oligomers, is an advantage for their use as probes and primers. Froehler et al teach that the purine-based oligomers have enhanced affinity for complementary nucleic acid sequences or enhanced nuclease stability and would have improved properties for

diagnostic applications. Thus, it would have been obvious to one skilled in the art at the time the invention was made to use purine-based analogues in the array synthesis and use the array in hybridization assays.

Applicant's arguments that the arrays synthesized using the purine analogues of Froehler et al would be different from the claimed method arrays. Applicants argue that the instant claimed method arrays have 'similar hybridization stability across the array', which was not taught by the combined teachings of the references Southern and Froehler et al.

Applicant's arguments have been considered and are not persuasive. In the instant claims the 'plurality of oligonucleoitde analogue probes bind to complementary target nucleic acids with a similar hybridization stability across the array...' is considered as a property of the probe and/or array. And the instant claim does not recite the property or the hybridization conditions which would result in any structural feature of the array, which is different as compared to the reference array. The arrays prepared using the combined teachings of Froehler et al modified purines in the method of Southern oligomer array synthesis, would have 'similar hybridization stability across the array'. The rejections of record are maintained in the absence of the special structural feature of the probe and/or array, which would result in the property 'similar hybridization stability across the array.' The rejections of record have been maintained for the reasons of record.

Conclusion

25. No claims are allowed.

26. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner is on Increased Flex Schedule and can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

PADMASHRI PONNALURI
PRIMARY EXAMINER

17 September 2004